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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/011,860	11/05/2001	Gust H. Bardy	032580.0042.CIP	6000

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No.	Applicant(s)	
	10/011,860	BARDY ET AL	
	Examiner	Art Unit	
	Kristen Mullen	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The finality of the previous office action is withdrawn in view of the newly discovered reference(s) to Heinrich et al. (2002/0082658). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 61-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 61 recites the limitation "the positive voltage portion" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 49-56, 59-60, 63-69 are rejected under 35 U.S.C. 102(e) as being anticipated by Heinrich et al. (2002/0082658).

Regarding claims 49, 53 and 54, Heinrich shows a method comprising generating energy, storing the energy; delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform having a peak voltage that is between approximately 25 V to approximately 50 V, between approximately 50 V to approximately 75 V, and between approximately 75 V to approximately 100 V (Para. [0064]).

With respect to claims 55, 59 and 60 Heinrich shows a method comprising generating energy, storing the energy; delivering the energy to the patient's heart; wherein the energy comprises a monophasic waveform having a pulse width that is between approximately 1 ms to approximately 40 ms, and between approximately 30 ms to approximately 40 ms (Fig. 5). For further explanation, in paragraph 0067, Heinrich gives the example that time period 500 is equal to 3 seconds, and 508 is equal to 1500 milliseconds. For time period 500, there are 12 tic marks shown and for time period 508, there are 9 tic marks shown in Fig. 5. Thus, each tic mark equals either 25 milliseconds or 16.6 milliseconds. Assuming that recharging 506, and 512 starts immediately following delivery of a pacing pulse 504, 510, the duration of the pacing pulse according to Fig. 5 would be 32.4 milliseconds or 50 milliseconds.

Regarding claims 50-52, Heinrich shows the energy comprises a monophasic waveform having a peak voltage that is between approximately 0.1 V to approximately 100 V, between approximately 0.1 V to approximately 25 V, and between approximately 25 V to approximately 50 V, (Para. [0064]).

With respect to claims 63 and 64, again refer to the timing shown in Fig. 5 and the description given in paragraph 0067.

Regarding claims 65-69, see Figs. 6-9 where Heinrich shows the implantable defibrillator is subcutaneously positioned between the third and fifth ribs, fourth and sixth ribs, sixth and eighth ribs, eighth and tenth ribs and tenth and twelfth ribs.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al. (2002/0082658). Heinrich discloses the claimed invention except for the monophasic waveform having a pulse width between approximately 2 milliseconds and approximately 10 milliseconds, between approximately 10 milliseconds and approximately 20 milliseconds, and between approximately 20 milliseconds and approximately 30 milliseconds. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform pulse width as taught by Heinrich with monophasic waveforms having a pulse width between approximately 2 milliseconds and approximately 10 milliseconds, between approximately 10 milliseconds and approximately 20 milliseconds, and between approximately 20 milliseconds and approximately 30 milliseconds, since applicant has not disclosed that these particular monophasic waveform pulse widths provide any criticality and/or unexpected results and it appears that the invention would perform equally well with any monophasic waveform pulse width such as approximately 32.4 milliseconds or 50 milliseconds as taught by Heinrich for applying pacing pulses.

Art Unit: 3762

8. Claims 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al. (2002/0082658) in view of Holmstrom (5,391,191).

With respect to claim 62, Heinrich fails to specifically disclose that the positive portion has a tilt between approximately 5% and 95%. Attention is directed to Holmstrom which shows that it is well known to utilize monophasic pacing pulses having a tilt between approximately 5% and 95% (Fig. 2). Therefore, it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the monophasic waveform as taught by Heinrich with a monophasic pacing pulses having a tilt between approximately 5% and 95%, since it is well known in the art to utilize monophasic pacing pulses having a tilt between approximately 5% and 95%.

Regarding claims 63, Heinrich and Holmstrom disclose the claimed invention except for the monophasic waveform having a tilt of 50%. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the tilt of the monophasic waveform as taught by Heinrich and Holmstrom with a 50% tilt, since applicant has not disclosed that this particular tilt provides any criticality and /or unexpected results and it appears that the invention would perform equally well with any tilt such as the 5% to 90% tilt taught by Heinrich and Holmstrom for applying pacing pulses.

Response to Arguments

9. Applicant's arguments with respect to claims 49-69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

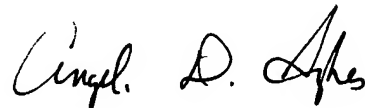
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



kdm



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